510(k): k110166

MAY 20 2011

5. 510(K) SUMMARY

510(k) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: January 6, 2011

Device Subject to this 510(k):

Trade Name:	ClearCut™ S Incisional Instruments
Common Name:	Ophthalmic Knife
Classification Name:	Manual ophthalmic surgical instrument

1. Predicate Devices:

The legally marketed device(s) to which we are claiming substantial equivalence are:

510(k) Number	Device
Exempt per 21CFR 886.4350	BD Beaver Safety Knife
Exempt per 21CFR 886.4350	KAI Safety Knife
Exempt per 21CFR 886.4350	Diamatrix ProTekt Safety Knife

2. Device Description:

The ClearCut™ S family of incisional instruments are manual ophthalmic surgical instruments used by surgeons to create surgical incisions during ophthalmic surgical procedures. Incisional instruments incorporating sharps protection features provide injury prevention to those who come in contact with the device. The instruments are designed with an integral guard that can be activated to place the blade in a safe or exposed condition. The product is

delivered to the user terminally sterilized by either gamma irradiation or ethylene oxide sterilization methods.

3. Indications for Use:

ClearCut™ S Incisional Instruments are sterile, single use disposable devices intended for using during ophthalmic surgical procedures.

4. Brief Summary of Nonclinical Test and Results:

The ClearCut™ S Incisional Instruments have been tested in conformance with the requirements set forth in the August 9, 2005, Guidance for Industry – "Medical Devices with Sharps Injury Prevention Features." In addition, biocompatibility evaluations of materials coming in contact with the patient have been performed according to ANSI/AAMI/ISO 10993. Details of this testing can be found in Section 13.

5. Comparison of Technological Characteristics to Predicate Devices:

A comparison table of the ClearCut™ S Incisional Instruments and predicate devices is on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Alcon Laboratories, Inc.
c/o Ms. Tonya Morgan
Senior Regulatory Affairs Analyst
6201 South Freeway
Fort Worth, Texas 76134

MAY 20 2011

Re: K110166
Trade/Device Name: ClearCut S Incisional Instruments
Regulation Number: 21 CFR 886.4350
Regulation Name: Manual ophthalmic surgical instrument
Regulatory Class: I
Product Code: HNN
Dated: April 12, 2011
Received: April 13, 2011

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110166

Device Name: ClearCut™ S Incisional Instruments (with Sharps Injury Protection)

Indications for Use:

ClearCut™ S Incisional Instruments are sterile, single-use disposable devices intended for use during ophthalmic surgical procedures.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) ____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110166